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For   : Method for Determining Care and Prevention Pathways for
               Clinical Management of Wounds

THIS APPLICATION CLAIMS THE BENEFIT OF U.S. PROVISIONAL APPLICATION NO.
60/116,349 FILED JANUARY 19, 1999.

Enclosed are :

[x] Specification with claims.

[x] _15_ sheets of drawing.   [x] Informal.

[ ] An assignment of the invention to _____

[ ] A certified copy of a _____ application, filed
     on _____ under Serial No. _____, the priority of which
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Method for Determining Care and Prevention Pathways for Clinical Management of Wounds

5   This application is related to co-pending application number 60/116,349 (filed January 19, 1999), which is incorporated herein by reference in its entirety.

The present invention relates to methods for consistently designating appropriate treatment protocols for patients, particularly protocols involving wounds or wound prevention.

10   A number of computer programs have been developed wherein a user, for example a care giver, inputs parameters indicative of a patient assessment into a computer and obtains a care plan as an output. Input parameters can include art recognized assessment parameters, such as those recommended by the National Pressure Ulcer Advisory Board. One example of such a computer program is the Wound and

15   Skin Intelligence System (WSIS) developed by Convatec and Applied Health Sciences. Other similar programs have been developed by Johnson & Johnson Medical (a division of Ethicon, Inc.) and Smith & Nephew, Ltd.

The effective use of such computer-based methods of deriving care plans often requires simultaneous proximity of the care giver to both the patient and the computer.

20   Care givers without ready access to a patient in close proximity to the programmed computer cannot effectively benefit from such computer-based approaches. Moreover, even when the programmed computer is available, the practicalities of providing care often makes it awkward to input data prior to rendering a treatment protocol.

Accordingly, there is a need for a method of selecting care plans for patients

25   customized to clinical assessment parameters that does not require immediate interaction with a computer, without compromising the quality of care provided. The present invention provides a method for correlating patient assessment parameters with appropriate treatment protocols. The method provides a visually keyed process to derive a care plan. The process does not require a computer, and when executed with a

30   computer is highly integrated with visual cues. Such a process can be embodied in devices that provide bedside tools to assist the care giver to make evidence-based decisions for the care of individuals, such as individuals at risk of forming wounds or individuals who already have wounds, such as a pressure ulcers.

Summary of the Invention

In one embodiment, the invention relates to a method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient
5   comprising: classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification; grading the wound or patient against defined
   . scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; and operating a visual decision tree device to show a
10   decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors. In some embodiments, at least one visual decision tree indicates two or more distinct decisions based on the grade of one or more second wound factors. In some embodiments, the
15   visual decision tree is a mechanical device. In some embodiments, the method can also comprise providing an interactive visual scoring sheet on which markers for the available scores for two or more wound factors are displayed; and marking the appropriate score for the two or more wound factors on the interactive visual scoring sheet, wherein the interactive visual scoring sheet contains a marker associated with one or more of the
20   scores identifying an addition to the treatment protocol.

In some embodiments, the invention relates to a method comprising classifying the wound against a defined wound classification scheme; grading the wound against defined scales for one or more second wound assessment factors; and operating visual decision tree device to show a decision or visual decision tree corresponding to the
25   wound classification or to a grade for a wound assessment factor, wherein at least one visual decision tree produced by the device dictates two or more distinct decisions based on the grade of one or more second wound assessment factors, and wherein the visual decision device identifies a treatment protocol for the wound classification and grades of the second wound assessment factors. In some embodiments of the invention, one of the
30   two visual decision tree devices is selected based on wound classification, and the selected visual decision tree device is operated to show a decision or decision tree corresponding to a grade for exudate amount. In some embodiments, the wound

classification scheme grades wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

The invention, in some embodiments, relates to a method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given

5   patient comprising: classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification; grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; operating visual decision tree device to show

10   the visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein at least one visual decision tree dictates two or more distinct decisions based on the grade of one or more second wound factors, and wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors; and marking a pre-defined display of treatment protocols

15   to identify the components of a treatment protocol identified by the method. In some embodiments, the method of the invention is operated through a graphical user interface on an electronic processor, resulting in a display of treatment protocols that matches a printed display used in manual operations of the method.

The invention also relates to a visual decision tree device for identifying a wound

20   care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: a mechanical or electronic device for identifying and displaying one of at least two decisions or visual decision trees based on one or more inputted wound factors according to a defined scale, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors. In some

25   embodiments, the sliding card comprises markers corresponding to a defined scale for classifying the wound or patient. In some embodiments, one or more sliding cards shows a visual decision tree and wherein the housing comprises a view window through which one or more visual decision trees corresponding to the wound classification can be viewed. In some embodiments, the visual decision tree device is mechanical and

30   wherein the slide card can be moved with respect to the housing to view through the view window any one of a plurality of individual decision trees displayed on the sliding card.

Brief Description of the Drawings

Figure 1 displays a wound assessment interactive visual scoring sheet.

Figure 2 displays a chronic wound management decision tool, which is a type of portable mechanical slide-rule visual decision tree device.

Figure 2A displays a schematic of a slide-rule visual decision tree device.

Figure 2B displays a first set of two exemplary sliding cards.

Figure 2C shows a second set of two exemplary sliding cards.

Figure 3 displays a schematic of a modular wound care protocol sheet.

Figure 4 displays a Patient Risk Assessment and Nurse Action Record, which is a type of interactive visual scoring sheet.

Figure 5 displays a Patient Risk Assessment Evaluation Tool, which is a type of portable mechanical slide-rule decision tree device.

Figure 5B displays a third set of two exemplary sliding cards.

Figure 6 displays a modular wound prevention protocol sheet.

Figure 7 displays a Wound Care and Assessment Record.

Figure 8 displays a pressure ulcer pathway decision tool, which is a type of a portable mechanical slide-rule visual decision tree device.

Figure 9 displays a wound assessment interactive visual scoring sheet.

Figure 10 displays a chronic wound management decision tool, which is a type of portable mechanical slide-rule visual decision tree device.

Figure 11 displays a Wound Care and Assessment Record.

Detailed Description of the Invention

FIG. 1 relates to an interactive visual scoring sheet **10** that can be used according to a preferred embodiment of the present invention. The interactive visual scoring sheet **10** can take substantially the same visually-cued form on the screen of a computer or personal device assistant (PDA). In electronic form, each scoring choice is separately on a viewing screen represented as in the paper example illustrated in FIG. **1**. The interactive visual scoring sheet **10** comprises a first defined scale **11** for classifying or grading a wound or patient according to a first wound factor **12** and a second defined scale **13** for classifying or grading the wound or patient for one or more second wound factors **14**. In some embodiments, the second defined scale **13** can include classifying or grading of the wound or patient according to: a defined wound assessment factor, a

defined wound risk assessment factor, some other classification of a patient's condition, or any combination of such factors. The first defined scale **11** and the second defined scale **13** can be represented by one or more markers **19** corresponding to one or more stages, grades or classifications. Markers **19** and associated criteria **15** can be indicated

5 on the visual scoring sheet **10**, for example, by indicia associated with markers **19**, including varying colors, numbers, letters, symbols, texture or any combination thereof. Optional associated criteria is provide a brief indication of the classifying or grading criteria. In some embodiments, the appropriate score for one or more classifying or grading factors can be marked on the interactive visual scoring sheet **10**. The criteria **15**

10 can be indicated in whole or in part on the visual scoring sheet **10**, or be referenced to criteria found elsewhere. The presence of at least a shorthand reference to the criteria is preferred. The second defined scales **13** can be with respect to one or more second wound factors **14**. Second wound factors **14** can, in some embodiments, be selected from any number of factors including but not limited to: exudate amount, necrotic tissue

15 amount, undermining, color of tissue around wound, granulating tissue, peripheral edema, peripheral induration and pain at wound. In some embodiments, second wound factors **14** can include, but are not limited to: sensory perception, moisture, activity, mobility, nutrition and friction & shear. In some embodiments, as shown in FIG. **9**, first wound factors **12** and second wound factors **14** can be selected from the group consisting

20 of: depth, exudate amount, exudate type, necrotic tissue amount, necrotic tissue type, undermining, surrounding skin color, granulation, peripheral edema, peripheral induration, pain at wound, nutrition, infection, edges, epithelization, functional ability, compliance and healthy margin.

The exemplary wound grading factors selected for FIG. **1** are a subset of the

25 exemplary wound grading factors selected for FIG. **9**. The selection of the particular factors of FIG. **1** as sufficient to predict patient care protocols represents an embodiment of the invention.

In some embodiments, one or more of the markers **19** for the first wound factor **12** or second wound factor **14** pertaining to a wound or patient condition can be

30 connected by connecting indicia **16** such as lines or arrows that identify one or more treatment protocol components **17**. One or more treatment protocol components **17** may be correlated to one or more markers **19**, for example by connecting indicia **16**, and may be written or referred to on the interactive visual scoring sheet **10**.

The interactive visual scoring sheet **10** can form, include or be used in reference to a visual decision tree **18**. Exemplary decision trees **18** are shown in FIG. 2. The visual decision tree **18** can comprise connecting indicia **16**. The visual decision tree **18** can dictate two or more distinct decisions based on one or both of the first or second

5 defined scales **11, 13** to identify a treatment protocol component **17** for the classified or graded factors. In FIG. 2, a first set of markers **19a** on a first sliding card **22a** are used to indicate values or stages of the first or second defined scales **11, 13**. A second set of markers **19b** are used on a second sliding card **22b** to indicate values or stages of the first or second defined scales **11, 13** in the example illustrated in FIG. 2.

10 In some embodiments, the first defined scale **11** can grade wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

To assess a wound, the wound is first visually inspected and the particular wound or patient parameters are determined, for example, according to one or more defined

15 scales for classifying or grading **11, 13**. The wound or patient parameters can then be recorded by marking or indicating them on the interactive visual scoring sheet **10**, for example by checking or circling appropriate markers **19**. Connecting indicia **16** and a visual decision tree **18** can then be used to identify appropriate protocol components **17** corresponding to the indicated markers **19**.

20 In one preferred embodiment of the invention depicted in FIG. 2, a visual decision tree device **20** is provided. A schematic of a visual decision tree device **20** is provided in FIG. 2A. In the nonlimiting example depicted in FIG. 2 , the visual decision tree device **20** is a mechanical slide-rule device made up of a first housing **21A** with a first view window **28A** and a first sliding card **22a**. Hingeably attached **HINGE** to the

25 first housing **21A** is second housing **21B** into which slides a second sliding card **22b**. The user inputs a value for one or more first **12** or second **14** wound factors according to the markers **19a, 19b** for the first or second defined scales **11, 13** displayed on the first or second sliding cards **22a, 22b,** for example by adjusting the position of the appropriate sliding card **22a** or **22b** within the appropriate housing **21A or 21B** such that an

30 appropriate marker **19a** or **19b** corresponding to the desired input value is displayed in view. Selection of the appropriate housing **21A** or **21B** and slide card **22a** or **22b** is determined in this example by connecting indicia **16** to the "Classification of Wound" score on the visual scoring sheet **10** of FIG. **1**.

QUESTION 1 (FIG. 2A) identifies which first or second wound factor 12, 14 is used to identify the appropriate marker 19a. The display of the appropriate marker 19a aligns the appropriate decision or visual decision tree 18a-18d in the view window 28. If present, QUESTION 2 of the displayed visual decision tree identifies a marker 19b for
5   which connecting indicia 16b identify appropriate wound care protocol components 17. In some instances, such as illustrated decision tree 18c, the decision tree identifies the wound care protocol component 17 from the marker 19a.

Wound care protocol components 17 can be grouped in modules on a wound care protocol sheet 30, as shown in FIG 3. In some embodiments, protocol components
10   17 for wound care of wound prevention are grouped in alpha-numeric groups or modules 31 that correspond to decision tree 18 outcomes. Based on the decision tree 18 outcomes, one or more protocol components 17 may be followed. The modules 31 can be an alpha-numerically labeled module, can include goals for treatment, multiple alternative therapies and recommended products for treatment.

15   The schematic of FIG. 2A shows a two part visual decision tree devices 20 comprising a housing 21 and a sliding card 22. The housing can comprise a top layer 23 and a bottom layer 24 made of, for example, heavy paper or plastic, joined along a top edge 25 and a bottom edge 26. A view window 28 is cut into the top layer 23. In some embodiments (not shown in FIG. 2A), the view window can be cut into the top layer or
20   the bottom layer. The sides of the top layer 23 and the bottom layer 24 are left open to allow the sliding card 22 to be inserted and moved within the housing 21. The top layer 23 can have a question QUESTION 1 printed on it, which governs where the operator should slide the sliding card 22 so that the appropriate marker from a first set of markers 19a is indicated in the view window 28. The sliding card 22 is slid within housing 21 to
25   a position with respect to the view window 28 where the QUESTION 1 on the top layer 23 is correctly answered by an appropriate marker 19a. A first set of connecting indicia 16a (e.g. arrows) points to one or more values for a second set of markers 19b in response to QUESTION 2. The operator selects a value from the second set of markers 19b in response to a second question QUESTION 2 found on the sliding card 22 and
30   performs the protocols (referenced as A, B or C in FIG. 2A at the bottom of the sliding card 22) that are indicated by a second set of arrows 16b.

In a particular example, the grade on first defined scale 11 on the interactive visual scoring sheet 10 of FIG. 1 identifies whether the slide rule of first housing 21A or

the slide rule of second housing **21B** shall be used (FIG. **2**). Referring to second housing **21B** of the visual decision tree device **20** of FIG. **2**, the score for alpha second defined scale **13a** identifies the position to which the ruler is adjusted. Referring to first and second sliding cards **22a**, **22b** of FIG. **2** and FIG. **2C**, in the first sliding card **22a**, one

5   dialed position (e.g., "0" on defined scale **13a** for first sliding card **22a** of FIG. **2C**) gives a wound care protocol component **17** depending on the score of beta second defined scale **13c**. Another dialed position (e.g., "2" on defined scale **13a** for second sliding card **22b** of FIG. **2C**) depends on the score of delta second defined scale **13d**. Two dialed positions (e.g., "1" or "3" on defined scale **13a** for first sliding card **22a** of FIG. **2C**)

10   directly indicate wound care protocol components **17**. Some dialed positions on the second sliding card depend on gamma second defined scale **13b**. Referring to FIG. **1**, additional wound care protocol components **17** are identified on the visual scoring sheet **10** by connecting indicia **16** associated with first defined scale **11** and beta, epsilon, zeta, eta and theta wound care protocol components **13B, 13E-13H** (FIG. **1**). Shown in FIGs.

15   **2B** and **2C** are particular exemplary first slide and second slide cards **22c, 22d** and **22a, 22b**, (respectively). Some embodiments, for example as shown in FIG. **5** and FIG. **5B**, can have a third sliding card **22e** and a fourth sliding card **22f** which can slide independently of each other to align a first marker **19a** or a second marker **19b** with a first view window **28a** and a second view window **28b**, respectively. These exemplary

20   slide cards are shown in FIGs **5B** and **5C**, respectively.

FIG. **2B** and FIG. **2C** display exemplary sets of first and second sliding cards **22a, 22b** which can be used to practice the invention. The sliding cards **22a, 22b** include separate visual decision trees **18e-18l** that can be aligned with a view window of a housing. Likewise, FIG. **2C** displays a set of first and second sliding cards **22a** and **22b**

25   that include visual decision trees **18m-18t**. For example, the first and second sliding cards **22c, 22d** of FIG. **2B** can be used in the visual decision tree device **20** of FIG. **10**. Likewise, the first and second sliding cards **22a, 22b** of FIG. **2C** can be used in the visual decision tree device **20** of FIG. **2**. In FIG. **2B**, first and second sliding cards **22c, 22d** have markers **19a** that correspond to a first defined scale **13a** and markers **19b** that

30   correspond to one or more second defined scales **13b, 13c, 13d**. Similarly, first and second sliding cards **22a, 22b** of FIG. **2C** have a first set of markers **19a** corresponding to a first defined scale **13a**, a second defined scale **13b**, a third defined scale **13c** and a fourth defined scale **13d**, which scales are defined for this example in the interactive

visual scoring sheet **10** of FIG. **1**. The example displayed in FIG. **2C** can be used in the visual decision tree decice **20** of FIG. **2**.

In preferred embodiments, a patient data sheet **40** can be combined with an interactive visual scoring sheet **10** and a wound care protocol sheet **30** in a patient care

5   into a patient diagnostic tool which can be, for example, a single double sided folder or folded sheet of paper. The patient diagnostic tool can be used in conjunction with one or more visual decision tree devices **20**.

The invention can comprise any number of embodiments, some of which are described in the Figures. In some embodiments of the invention, the interactive visual

10   scoring sheet can have different first defined scale **11** and different second defined scale **12** for wound classifying or grading or patient risk assessment. FIG. **1**, FIG. **4** and FIG. **9** show different visual scoring sheets **10** that can be used to practice the invention. FIG. **2**, FIG. **5**, FIG. **8** and FIG. **10** show different visual decision tree devices **20** that can be used to practice the invention. FIG. **3** and FIG. **6** show different wound care protocol

15   sheets **30** that can be used to practice the invention. FIG. **7** and FIG. **11** show different patient data sheets **40** that can be used to practice the invention. The figures are provided as examples of possible embodiments of elements which may be used to practice the invention, and should not be construed to limit the scope of the invention.

20   **Definitions**

The following terms shall have, for the purposes of this application, the respective meaning set forth below.

* **interactive visual scoring sheet.** An interactive visual scoring sheet is printed or

25   electronic sheet on which scoring choices of wound factors are displayed in a form in which the scores can be visually marked.

* **matching electronic display.** An electronic display of treatment protocols matches a traditionally printed display if the treatment options displayed match.

* **slide rule device.** A mechanical visual decision tree device, which can include, for

30   example, a slide rule or slide wheel device.

• **visual decision tree.** A visual decision tree is a representation of two or more decisions, with the appropriate decision indicated visually based on the score of at least one wound factor.

• **visual decision tree device.** A visual decision tree device is a device, electrical or mechanical, which can provide a visual image of a decision or decision tree based on an inputted wound care or wound prevention assessment value. The device produces two or more separate visual images of a decision or decision tree, including at least one decision tree depending on the input value. With a mechanical device, such as a slide rule or slide wheel, "inputting" comprises adjusting the mechanical device to correspond to the input value.

• **wound factor.** A wound factor is a wound assessment factor for which there is a defined grading scale or a wound risk assessment factor for which there is a defined grading scale.

The following examples further illustrate the present invention, but of course, should not be construed as in any way limiting its scope.

Example 1 - Wound Treatment

One example of a method for assessing the status of a patient and derivation of a care plan, or protocol, for wound treatment is as follows. A front cover of a Wound Care & Assessment Record (FIG 7) can be completed and included to identify the patient and care giver and to record dates and details of treatment, or the like. A Wound Assessment Record (Pressure Sore Status Tool), a type of interactive visual scoring sheet (FIG. 1) is completed by circling appropriate assessment scores for each factor (exudate amount, necrotic tissue amount, undermining, surrounding skin color, granulation, peripheral edema, peripheral induration, and pain). Using the interactive visual scoring sheet of FIG. 1, a care giver, upon examining a wound, classifies the wound as Stage 3 according to the first defined scale for classification. The care giver then assigns the following scores to assessing the wound according to their respective second defined scale for grading the wound: Exudate amount = 3; Necrotic Tissue Amount = 3; Undermining = 2; Color of Tissue Around Wound = 3; Granulating Tissue = 3; Peripheral Edema = 1; Peripheral Induration = 0; Pain at Wound = 4.

Next, the Chronic Wound Management Pathway Decision Tool, a type of portable mechanical slide-rule visual decision tree device, of FIG. **2** is used as follows: (i) using the Exudate Amount score selected from the interactive visual scoring sheet of FIG. **1**, go to the colored side of the slide rule recommended; (ii) from the interactive

5   visual scoring sheet of FIG. **1**, identify the score checked for exudate amount and move the slide rule to the score for exudate amount; (iii) follow the arrows, answer all questions and select the appropriate nurse action items; (v) circle the numbers in the Nurse Action Report (Care Plan), a type of modular wound care protocol (FIG. **3**).

Accordingly, the care giver having assessed the wound, follows the decision tree

10   provided in FIG. **1** and FIG. **2** to arrive at a care plan from FIG. **3**. Following the wound assessment data detailed in the above example, this process is as follows. First, the caregiver notes that the marker for Stage 3 in the Classification of Wound scale has two arrows connected to it: a vertical arrow (which points to "See Red Side of Nurse Action Guide") and a horizontal arrow that passes through the marker pointing from left to right

15   (which points to "Nurse Action 5"). The vertical arrow requires the care giver to consult the red side of the decision tool (i.e. Nurse Action Guide), which corresponds to the top section of FIG. **2**. Beginning at "START HERE" in the upper portion of the tool represented in FIG. **2**, the care giver slides the card in the housing so that the number determined for Exudate Amount in the wound assessment is showing (i.e. "3" in the

20   example). Once this is done, an arrow on the sliding card points to Nurse Actions 2 and 2C, which are found in FIG. **3**, with accompanying text in Sections 2 and 2A of Table 1. The care giver then follows the protocols corresponding to Nurse Actions 2 and 2C.

Returning to the interactive visual scoring sheet of FIG. **1**, the care giver next visually notes all factors indicated that are intersected by a line with an arrow attached as

25   an endpoint (necrotic tissue amount, surrounding skin color, granulation, peripheral edema, peripheral induration, pain at wound and nutrition). If a line attached to the box is checked or circled then the care giver follows through to the end of the arrow where one finds the appropriate nurse action referenced. The care giver then records the nurse action on the modular wound care protocol (e.g., Nurse Action Report (Care Plan) of

30   FIG. **3**) by circling it. If a checked or circled box or marker does not have a line attached to it then the care giver is not required to do anything further for that marker. Finally, after circling all numbers on the modular wound care protocol (e.g. FIG. **3**), the care giver follows the care plan and proceeds to take action.

Returning to the visual scoring sheet results in the above example, the horizontal arrow horizontally intersecting marker 3 for classification of wound and pointing to "Nurse Action 5" indicates that the care giver should also perform Nurse Action 5 (which is found in Section 5 of Table 1).

5   Next, the care giver can examine each marker indicated in the grading scales (from "Exudate Amount" down to "Pain @ Wound") and look for horizontal arrows passing through a marker. For instance, the marker for "3" indicated for "Necrotic Tissue Amount" has an arrow pointing to "Nurse Action 3". Accordingly, the care giver would then perform the protocol for Nurse Action 3 (found in FIG. 3, with text in

10   Section 3 of Table 1). The results indicated above for "Granulating Tissue" (3) and "Peripheral Edema" (1) both require Nurse Action 4, however such multiple indications for any given Action do not increase the number of times the Action must be performed (i.e. in this example, Nurse Action 4 is performed once, not twice). Finally, the marker for "Pain @ Wound" (4) intersects an arrow that points to Nurse Action 6. Thus, in

15   following the example above, the care giver would circle and perform Nurse Actions 2, 2C, 3, 4, and 5 as indicated in FIG. 3 by circles 32.

Table 1: Possible text for modular wound care protocol Sheet (FIG. 3)

Table 1, SECTION 1	
1	***GOAL* Maintain intact skin: Beware of deep tissue damage that may be irreversible.**

Assess knowledge of patient/caregiver on risk of skin breakdown and methods of prevention. Reduce effect of risk factors. **Pressure:** regular repositioning and pressure distribution (pillows, devices) **Shear/friction:** Apply protective ointment or moisture retentive dressing to reduce friction **Excess Moisture:** Clean at routine intervals with a skin cleanser, pat dry. Protect skin from moisture and irritants with a moisture barrier and/or absorbent dressings/absorbent products. **Dryness:** Follow routine bathing procedure with gentle cleansers. Moisturize immediately after bathing. Apply body cream for areas prone to extreme dryness. **Trauma/Skin Tears:** Apply protective coverings to protect against friction and/or pressure **Nutrition altered:** Nutritional Support Action Taken _____ _____ **SKIN CARE PRODUCTS:** **Patient Bathing** ☐ Aloe Vesta 2-n-1 Body Wash/Shampoo *Days Used* M T W T F S S ☐ Sensi-Care Perineal/Skin Cleanser *Days Used* M T W T F S S	☐ Aloe Vesta 2-n-1 Skin Perineal/Skin Cleanser *Days Used* M T W T F S S ☐ Other _____ *Days Used* M T W T F S S **Moisture Barriers** ☐ Aloe Vesta 2-n-1 Protective Ointment *Days Used* M T W T F S S ☐ Sensi-Care Protective Barrier *Days Used* M T W T F S S ☐ Other _____ *Days Used* M T W T F S S **Skin Moisturizers** ☐ Aloe Vesta 2-n-1 Skin Conditioner *Days Used* M T W T F S S ☐ Sensi-Care Protective Barrier *Days Used* M T W T F S S ☐ Other _____ *Days Used* M T W T F S S **Moisture Retentive Dressings** ☐ DuoDERM Extra Thin Size_____ *Days Used* M T W T F S S **Absorbent Dressings** ☐ Lyofoam Size_____ *Days Used* M T W T F S S ☐ Hydrosorb Size_____ *Days Used* M T W T F S S ☐ Other _____ Size_____ *Days Used* M T W T F S S **Protective Coverings** ☐ Tubifast *Days Used* M T W T F S S ☐ Tubipad *Days Used* M T W T F S S ☐ Arthropad *Days Used* M T W T F S S ☐ Other _____ *Days Used* M T W T F S S

Table 1, SECTION 2			
2	***GOAL* Obtain a clean wound bed.**	**2C**	***GOAL* Absorb excess exudate/maintain moist wound environment.**

PRODUCTS:

<div style="display:flex">

PRODUCTS: (left)

Wound Cleansing
- ☐ SAF Clens
  Days Used M T W T F S S
- ☐ Other _____
  Days Used M T W T F S S

2A	***GOAL* Provide moist wound environment.**

PRODUCTS:

Primary Dressing
Moisture Retentive Dressing
- ☐ DuoDERM CGF   Size_____
  Days Used M T W T F S S
- ☐ Other _____ Size_____
  Days Used M T W T F S S

Secondary Dressing   Not applicable.

PRODUCTS: (right)

Primary Dressing
Exudate Management
- ☐ AQUAGEL Hydrofiber   Size____
  Days Used M T W T F S S
- ☐ Kaltostat   Size____
  Days Used M T W T F S S
- ☐ Lyofoam Foam Dressing   Size____
  Days Used M T W T F S S
- ☐ Other _____
  Days Used M T W T F S S

Secondary Dressing
Moisture Retentive Dressing
- ☐ DuoDERM CGF   Size____
  Days Used M T W T F S S
- ☐ Other _____ Size____
  Days Used M T W T F S S

PRODUCTS:

</div>

2B	***GOAL* Assist in autolytic debridement and removal of necrotic tissue / Provide moist wound environment.**

PRODUCTS: (left)

Primary Dressing
Wound Hydration
- ☐ DuoDERM Hydroactive Gel
  Days Used M T W T F S S
- ☐ Other _____
  Days Used M T W T F S S

Secondary Dressing (right)
Moisture Retentive Dressing
- ☐ DuoDERM CGF   Size_____
  Days Used M T W T F S S
- ☐ Other _____ Size_____
  Days Used M T W T F S S

Table 1, SECTIONS 3 AND 4	
3	***GOAL*** **Reduce devitalized tissue.**

PRODUCTS:

Debridement
The suggested topical treatments will facilitate autolytic debridement. Autolytic debridement is usually not recommended for patients with infected wounds or patients at increased risk of infection.
☐ Surgical by   ☐ MD   ☐ Nurse   ☐ Enzymatic
Days Used M T W T F S S
☐ Autolytic   ☐ Mechanical
Products Used

_____

_____

4	***GOAL*** **Identify infection and institute medicine treatment.**

If infection is confirmed, perform Nurse Action 4A. If infection is not confirmed, perform Nurse Action 4B.
 	
Nurse Action 4A: Appropriate medical treatment for infection should be initiated or continued. DuoDERM CGF dressings can be continued during the treatment of infection at the discretion of the clinician.
 	
Nurse Action 4B: Evaluate for signs of infection. If not infected, moisture retentive dressing should extend beyond reddened area to protect skin.
 	
Minimize friction and shear forces to surrounding skin.
 	
Action Taken and Products Used to Treat Infection_____
_____
	PRODUCTS:
	
	Primary Dressing
	Wound Hydration
	☐ DuoDERM Hydroactive Gel
	  Days Used M T W T F S S
	☐ Other _____
	  Days Used M T W T F S S
	Secondary Dressing
	Moisture Retentive Dressing
	☐ DuoDERM CGF Size_____
	  Days Used M T W T F S S
	☐ Other _____ Size_____
	  Days Used M T W T F S S

Table 1, SECTIONS 5 AND 6		
5	***GOAL* .Prevent further skin breakdown and stimulate healing.**	
Relieve pressure **PRESSURE ULCER** --institute turning schedule for patient --utilize pressure reduction device(s) Action Taken and Products Used _____ _____	☐ Bed/Mattresses_____ ☐ Devices_____ ☐ Other_____	
VENOUS STASIS ULCER Compression Therapy (30-40mm/Hg pressure to heal ulcer)	**PRODUCTS:** ☐ SurePress™ High Compression Bandage ☐ SurePress Absorbent Padding ☐ UNNA-FLEX *Days Used* M T W T F S S	
DIABETIC FOOT ULCERS Off loading of pressure	Action Taken and Products Used _____ _____	
6	***GOAL* Pain Management**	
Provide analgesics. Cover with Moisture Retentive Dressings. Action Taken and Products Used _____ _____		

Table 2: Possible text for modular wound care protocol Sheet (FIG. 3)

Nurse Action Report (Care Plan) Circle or check off the appropriate treatments and indicated products used.

5

Solutions for Would Treatment

Table 2, SECTION 1	
1	***GOAL* Maintain intact skin: Beware of deep tissue damage that may be irreversible.**

Assess knowledge of patient/caregiver on risk of skin breakdown and methods of prevention.
 	
Reduce effect of risk factors.
 	
Pressure: regular repositioning and pressure distribution (pillows, devices)
 	
Shear/friction: Apply Skin Care products (lubricate) *or* Moisture Retentive Dressing (reduce friction)
 	
Excess Moisture: Manage with Skin Care Products or Moisture Retentive Dressing (protection) and incontinence products
 	
Dryness: Use Skin Care bathing and protection products.
 	
Nutrition altered: Nutritional Support
 	
Action Taken _____ _____
	PRODUCTS:
	
	Patient Bathing
	☐ Aloe Vesta Body Wash/Shampoo
	  Days Used M T W T F S S
	☐ Septi-soft Body Wash/Shampoo
	  Days Used M T W T F S S
	☐ Other _____
	  Days Used M T W T F S S
	Skin Protection
	☐ Aloe Vesta Skin Cream
	  Days Used M T W T F S S
	☐ Aloe Vesta Protective Ointment
	  Days Used M T W T F S S
	☐ Other _____
	  Days Used M T W T F S S
	Incontinence Care
	☐ Aloe Vesta Antifungal Ointment
	  Days Used M T W T F S S
	☐ Aloe Vesta Protective Ointment
	  Days Used M T W T F S S
	☐ Aloe Vesta Perineal Foam
	  Days Used M T W T F S S
	☐ Aloe Vesta Perineal Solution
	  Days Used M T W T F S S
	☐ Ilex Skin Protectant Paste
	  Days Used M T W T F S S
	☐ Other _____
	  Days Used M T W T F S S

Table 2, SECTIONS 2 and 3 - Debride Necrotic Tissue			
2	**Debride necrotic tissue.**		
3	***GOAL*** **Provide systematic support/preventive measures to facilitate healing based on general patient assessment findings**		
3	**Wound Cleansing.**	**3A**	**Moisture Retention**

<table>
<tr>
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PRODUCTS:

☐ Saline
Days Used M T W T F S S
☐ SAF Clens
Days Used M T W T F S S
☐ Other
Days Used M T W T F S S

</td>
<td colspan="2">

Primary Dressing:

PRODUCTS:

☐ DuoDERM CGF
Days Used M T W T F S S
☐ DuoDERM Extra Thin
Days Used M T W T F S S
☐ Signadress
Days Used M T W T F S S
☐ Other
Days Used M T W T F S S

Secondary Dressing: N/A

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</tr>
<tr>
<td>**3B**</td>
<td>**Wound Hydration**</td>
<td>**3C**</td>
<td>**Exudate Management**</td>
</tr>
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<td colspan="2">

Primary Dressing: *Wound Hydration:*

PRODUCTS:

☐ DuoDERM Hydroactive CGF
Days Used M T W T F S S
☐ SAF Gel
Days Used M T W T F S S
☐ Other
Days Used M T W T F S S

Secondary Dressing: *Moisture Retentive Dressing:*

PRODUCTS:

☐ DuoDERM CGF
Days Used M T W T F S S
☐ DuoDERM Extra Thin
Days Used M T W T F S S
☐ Signadress
Days Used M T W T F S S
☐ Other
Days Used M T W T F S S

</td>
<td colspan="2">

Primary Dressing: *Exudate Management:*

PRODUCTS:

☐ Aquacel Hydrofiber
Days Used M T W T F S S
☐ Kaltostat Dressing
Days Used M T W T F S S
☐ Carboflex Odor
Days Used M T W T F S S
☐ Other
Days Used M T W T F S S

Secondary Dressing: *Moisture Retentive Dressing:*

PRODUCTS:

☐ DuoDERM CGF
Days Used M T W T F S S
☐ DuoDERM Extra Thin
Days Used M T W T F S S
☐ Signadress
Days Used M T W T F S S
☐ Other
Days Used M T W T F S S

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</table>

Table 2, SECTIONS 4, 5, 6, and 7	

4 — ***GOAL* Reduce devitalized tissue.**

Debridement: The suggested topical treatments will facilitate autolytic debridement. Autolytic debridement is usually not recommended for patients with infected wounds or patients at increased risk of infection.

☐ Surgical by   ☐ MD   ☐ Nurse   ☐ Enzymatic

Days Used M T W T F S S

☐ Autolytic   ☐ Mechanical

Products Used

_____

_____

_____

5 — **If infection is confirmed, perform Nurse Action 5A. If infection is not confirmed, perform Nurse Action 5B.**

5A	**5B**
Appropriate medical treatment for infection should be initiated or continued. DuoDERM CFG dressings can be continued during the treatment of infection at the discretion of the clinician.	Evaluate for signs of infection. If not infected, moisture retentive dressing should extend beyond reddened area to protect skin. Minimize friction and shear forces to surrounding skin.

Action Taken and Products Used to Treat Infection

_____

_____

_____

6 **Relieve Pressure**	**7** **Provide analgesics. Cover with Moisture Retentive Dressings.**
Action Taken and Products Used	Action Taken and Products Used
_____	_____
_____	_____
_____	_____

Table 2, SECTION 7	
8	

<table>
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Has the patient been screened for nutritional deficiency indicators in the past month.

☐ No   ☐ Yes → Rescreen
↓   Monthly

Evaluate the patient for presence of any of the following nutritional deficiency indicators.

    ☐ Elderly
    ☐ Infection
    ☐ Wound
        ☐ Systemic
        ☐ Other _____
    ☐ Score of <18 on Braden Scale
    ☐ Poor response to current would treatment for past 2-4 weeks
    ☐ Recent unintentional weight loss/gain

</td>
<td>

☐ Functional limitations
    ☐ Chewing/swallowing
    ☐ Mobility
    ☐ Hearing/speech
    ☐ Vision
    ☐ Dexterity
☐ Altered mental state ☐ Medical Condition
    ☐ Diabetes
    ☐ Arterial Insufficiency
    ☐ Cardiovascular disease
    ☐ Venous Insufficiency
    ☐ Incontinence
    ☐ Gastrointestinal disorder
    ☐ Immunosuppression
☐ Drug Therapy
    ☐ Corticosteroids
    ☐ Immunosuppressants
    ☐ Antitumor agents

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</table>

If any of the above is checked, perform Nutrition Assessment .

Example 2 - Wound Prevention

5   One example of a method for assessing the status of a patient and derivation of a care plan, or protocol, for wound prevention is as follows. A Patient Risk Assessment Evaluation Sheet (FIG. **4**), a type of interactive visual scoring sheet, is completed by a care giver using a variation of the Braden Scale by circling appropriate assessment scores for each risk factor (sensory perception, moisture, activity, mobility, nutrition and

10   friction & shear). Second, the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. **5** is used as follows: the slide rule is moved to each respective checked score from the Patient Risk Assessment Record (FIG. **4**) for each respective risk factor. The arrows downward in the slide rule are followed to select the nurse actions (letters A to X) that correspond with the information contained in the Patient Risk Assessment Record.

15   Finally, all letters in the a modular wound prevention protocol sheet (also called a Nurse Action Report, FIG. **6**) selected from the slide rule are circled. Circled protocols are then

followed. Table 3 provides the text of protocols that can be arranged on a single wound prevention protocol sheet, as shown schematically in FIG. **6**.

The method of practicing the invention is outlined in the example below. The care giver obtains the Patient Risk Assessment Record (FIG. **4**) and the Slide Rule

5   Pressure Ulcer Pathway Decision Tool of FIG. **5**, and then examines a patient. The care giver obtains the following assessments: Sensory Perception = 3; Moisture = 1; Activity = 2; Mobility = 2; Nutrition = 4; Friction & Shear = 3. After recording this assessment on the Patient Risk Assessment Record (FIG. **4**), the care giver follows any arrows in FIG. **4**. Specifically, the Moisture grading of 1 points to "See Moisture Chart", the

10   Activity grading of 2 points to "See Activity Chart", the Nurtition grading of 4 has no arrows and the Friction & Shear grading of 3 has no arrows.

The care giver the uses the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. **5**, and follows the decision tree for moisture. The first and second sliding cards **22e, 22f** of FIG. **5** are displayed in FIG. **5B**. Answering all questions, the care giver

15   performs all nurse actions that apply. For instance, if the patient does not suffer urinary or fecal incontinence, but does perspire the care giver would perform Nurse Action F, but <u>not</u> nurse actions A, B, C, D, or E. Further consulting FIG. **5**, the care giver slides the sliding card to an Activity rating of 2 and follows the arrows and protocols indicated in the view window (namely Nurse Action K, but not Nurse Action J since the Braden

20   Scale total score is 15 for this patient). The care giver then slides the sliding card until the grade of 3 for nutrition number is indicated in the view window. The care giver then follows protocols indicated in the Nurtition window. For the patient above, given that the patient is only fed orally, Nurse Action P would be performed by the care giver, but not Nurse Actions O or V. The care giver then consults the Friction and Shear section

25   of FIG. **5**. Noting that a score of 3 for Friction & Shear does not appear with any arrows, no further Nurse Action protocols need be performed. Thus, for the patient of this example, as shown in the Nurse Action Report Sheet (FIG. **6**), Nurse Action protocols F, K and P should be performed by the care giver.

Table 3: Possible text for modular wound prevention protocol sheet (FIG. 6)

Nurse Action Report Circle or check off the appropriate treatments and indicate products used.

5

Table 3, Section 1: Managing Moisture

A. If related to tube feeding, lower volume, increase delivery time, decrease osmolality, add filler or add bulking agent. (*Consult dietary plan*). If nutritional intake is entreal, determine potential causes of loose stool. Check for impaction. If frequent, apply fecal incontinence pouch. If persistent, obtain order for anti-diarrheal medication.

☐ Products used

_____

_____

B. Cleanse skin promptly and thoroughly with incontinence skin cleanser or non-drying soap and pat dry.

☐ Aloe Vesta Perineal Solution
☐ Aloe Vesta Perineal Foam
☐ Other_____

_____

C. If taking diuretic, schedule in late afternoon. If moisture is due to regular nighttime urinary incontinence, consider one scheduled toileting during the night.

_____

_____

D. Implement q 2h toileting schedule (waking hours) and offer fluids every 2 hours during waking hours. Cleanse skin promptly with non-drying soap or incontinence skin cleanser, pat dry. Use moisture barrier to protect skin. Use only underpads that wick fluid away from the skin, leaving surface next to skin dry. Cleanse skin, incontinence cleanser or non-drying soap.

☐ Aloe Vesta Perineal Solution
☐ Aloe Vesta Perineal Foam
☐ Aloe Vesta Protective Ointment
☐ Other_____

_____

E. Use moisture barrier to protect surrounding tissue. Pouch heavily draining wound (Consult ET).

☐ Aloe Vesta Protective Ointment
☐ Other_____

_____

F. Check linens every two hours. Change linens as needed. Bathe daily to remove waste products left by perspiration. Clean skin folds thoroughly, but gently and pat dry. Consider different mattress or support surface if a non-breathable covering is aggravating problem.

☐ Septi Soft Body Wash & Shampoo
☐ Other_____

_____

Table 3, Section 2: Activity

G. Implement plans for small shift in position.

_____

_____

H. Use pressure reducing chair seating. Implement q 1h chair repositioning schedule.

☐ Positioning Cushion

I. Teach patient to do lift-off's 15 minutes.

_____

_____

J. When in bed, use foam wedges for lateral position and pillow to bridge sacrum. Avoid lateral positioning of more than 30 degrees.

☐ Positioning Cushion
☐ Pillow
☐ Other_____

K. Place pressure reducing surface on bed or chair. Avoid positioning directly on trochanter.

☐ Mattress Overlay
☐ Positioning Cushion
☐ Other_____

L. When in bed, use positioning devices to suspend heels so they do not touch the mattress. Use good positioning to keep knees from touching. Avoid elevating HOB more than 30 degrees, except for brief periods.

☐ Positioning Cushion
☐ Other_____

M. Use pressure reducing chair seating. Implement q 1h chair repositioning schedule.

☐ Positioning Cushion
☐ Other_____

N. Implement q 2h turning schedule. If patient can make purposeful movements, encourage frequent turning/shifts in body position.

_____

_____

Table 3, Section 3: Managing Nutrition

O. If dietician was not consulted to determine the match between the patient condition, metabolic need, and formula type and amount - initiate dietary consult to do so now.

_____

_____

P. Give protein supplement at bedtime.

☐   Protein Supplement

Q. If the patient is receiving less than optional amount because of high residual volumes in stomach, notify physician and obtain medication orders to decrease gastric retention or obtain orders for parental nutrition.

If the patient is receiving less than the optimal amount because of inadequate ordering or changes in patient's condition, request new orders from physician or dietician.

R. Request order for multi-vitamin with Vitamins A, C, and Zinc. Obtain dietary consult if these interventions are not successful within 24 hours. Change diet to reflect food preferences/habits or to address any problems with chewing or swallowing. Create caloric intake plan and monitor goal achievement.

☐   Vitamin Supplement

S. Attempt protein supplement at meals and before bedtime.

☐   Protein Supplement

T. Give supplement twice a day.

☐   Protein Supplement
☐   Other_____

U. Initiate physician contact to clarify goals of treatment and/or to examine avenues to improve nutritional intake.

_____

_____

V. Reassess periodically if patient's condition changes.

Table 3, Section 4: Friction & Shear

W. Avoid raising HOB>30 degrees. Use lifting sheet to move patient in bed; do not drag patient across the linens. Use elbow and heel protectors if these prominences are exposed to friction. Use a sheepskin under spastic extremities. (Do not place under trunk.)

☐   Positioning Cushion
☐   Heel or Elbow Protectors

X.   Consider a trapeze, if patient has sufficient upper body strength to assist in moves.

Patient_____   Date:_____

Nurse_____   Physician_____

Notes_____

Further information for products referred to in the above table is listed below.

5

- AQUACEL Hydrofiber: a wound dressing comprising a non-woven pad composed of sodium carboxymethylcellulose fibers. The dressing is highly absorbent and forms a soft gel interacts with wound exudate and forms a soft gel which maintains a moist environment for wound healing.

10

- Arthropad: Tubigrip Arthropad is a wrapping bandage designed to provide lasting, effective support with complete freedom of movement for the patient. The Tubigrip Arthropad provides tissue support in the management of soft-tissue injuries and general edema and may be used as a pressure dressing.

15

- Carboflex Odor: A sterile non-adhesive dressing with an absorbent wound contact layer (containing Alginate and Hydrocolloid), an activated charcoal pad and a smooth water-resistant top layer.

20 • DuoDERM Extra Thin: highly flexible, control gel formula dressing made for use on dry to lightly exudating wounds. The dressing conforms to the body,

cleans by autolytic debridement and is a highly effective secondary dressing for wound fillers.

5
- DuoDERM Hydroactive Gel: a sterile gel comprising natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a clear, viscous vehicle.

- DuoDERM Hydroreactive Gel: a sterile gel composed of natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a clear, viscous vehicle. This product is designed for the management of partial and full-thickness wounds and creates a
10 moist healing environment around a wound which helps to promote the natural autolytic process of debridement.

- DuoDERM CGF: is a dressing that interacts with wound exudate to produce a
15 soft mass that enables removal of the dressing with little or no damage to newly formed tissues. The dressing helps isolate the wound against bacterial, viral (HIV-1 and HBV) and other external contamination and can remain in place up to seven days.

20 - Kaltostat: a sterile non-woven dressing of calcium-sodium alginate fiber which can absorb wound exudate or saline and convert from a firm gel/fiber mat. The gel forms a moist, warm environment at the wound interface.

- Kalostat Dressing: a highly absorbent calcium alginate dressing derived from
25 natural seaweed designed to absorb exudate and control minor bleeding. The dressing is easy to apply, can remain in place up to seven days, and may be used on moderately to heavily exuding wounds.

- Lyofoam Foam Dressing: A polyurethane foam dressing comprising an
30 absorptive hydrophilic contact surface and a secondary outer foam layer through which the aqueous component can be lost by evaporation. The dressing is freely permeable to gases and water vapor but resists strike-through of aqueous solutions and exudate, as the outer layer has hydrophobic properties.

35 - SAF Gel: an alginate containing formulation designed for multiple uses. The gel is indicated for use on chronic and acute wounds such as dry wounds, pressure ulcers (Stages I to IV) and stasis ulcers.

- SAF Clens: a wound cleaner that has a dual surfactant formulation designed for
40 cleansing of chronic wounds, including superficial, partial-thickness, dry or nectotic wounds. The wound cleanser is nontoxic, noniritating and comes in no-rinse formula.

- Signadress: a hydrocolloid dressing comprising an inner (wound contact) layer of
45 hydrocolloids contained within an adhesive polymer matrix and an outer layer of polyurethane film. The dressing also has a product identification mark (ConvaTec registered tear drop trademark) and a visible (SignaDRESS) change indicator guide printed on the film backing.

- Sure Press High Compression Bandage and Sure Press Absorbant Padding: The SurePress High Compression Bandage System is comprised of two layers: the SurePress High Compression Bandage, a washable bandage made from high-quality blend of cotton-viscose, nylon and LYCRA, and the SurePress Absorbent Padding for use as an underlayer. The System can be used for management of venous leg ulcers and associated conditions, and is contraindicated for the management of arterial and mixed venous/arterial ulcers and legs with an ankle circumference less than 18 cm.

- Tubipad: is made from a layer of polyurethane foam banded to a length of elastic tubular bandage that is used for the protection of heels, elbows and knees.

- UNNA-FLEX: is an elastic bandage that provides compression, for instance to improve venous return. The bandage can be self-adherent or in the form of a boot.

One will appreciate that products listed in the table above, or functional equivalents, are commercially available from a variety of vendors.

All publications and references, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference in their entirety as if each individual publication or reference were specifically and individually indicated to be incorporated by reference herein as being fully set forth. Any patent application to which this application claims priority is also incorporated by reference herein in its entirety in the manner described above for publications and references.

While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations in the preferred devices and methods may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications encompassed within the spirit and scope of the invention as defined by the claims that follow.

- 28 -

What is claimed:

1.	A method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising:

classifying the wound or patient against a defined scale for a first wound factor,

5	which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification;

grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; and

10	operating a visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors.

15	2.	The method of claim 1, wherein the visual decision tree is a mechanical device.

3.	The method of claim 1, wherein at least one visual decision tree indicates two or more distinct decisions based on the grade of one or more second wound factors.

20

4.	A method of claim 1 of identifying a wound care protocol appropriate for a given wound comprising:

classifying the wound against a defined wound classification scheme;

grading the wound against defined scales for one or more second wound

25	assessment factors; and

operating visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a grade for a wound assessment factor, wherein at least one visual decision tree produced by the device dictates two or more distinct decisions based on the grade of one or more second wound assessment factors,

30	and wherein the visual decision device identifies a treatment protocol for the wound classification and grades of the second wound assessment factors.

5.   The method of claim 4, wherein one of the two visual decision tree devices is selected based on wound classification, and the selected visual decision tree device is operated to show a decision or decision tree corresponding to a grade for exudate amount.

5

6.   The method of claim 4, wherein the wound classification scheme grades wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

10   7.   The method of claim 1, further comprising:

providing an interactive visual scoring sheet on which markers for the available scores for two or more wound factors are displayed; and

marking the appropriate score for the two or more wound factors on the interactive visual scoring sheet,

15   wherein the interactive visual scoring sheet contains a marker associated with one or more of the scores identifying an addition to the treatment protocol.

8.   A method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising:

20   classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification;

grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors;

25   operating visual decision tree device to show the visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein at least one visual decision tree dictates two or more distinct decisions based on the grade of one or more second wound factors, and wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound

30   factors; and

marking a pre-defined display of treatment protocols to identify the components of a treatment protocol identified by the method.

9.   The method of claim 8, wherein the method is operated through a ....
interface on an electronic processor, resulting in a display of treatment protocols that
matches a printed display used in manual operations of the method.

5   10.   A visual decision tree device for identifying a wound care protocol for a
given wound or wound prevention protocol appropriate for a given patient comprising:
        a mechanical or electronic device for identifying and displaying one of at
least two decisions or visual decision trees based on one or more inputted wound factors
according to a defined scale,
10   wherein the visual decision tree device identifies at least one component of a
treatment protocol for the graded wound factors.

        11.   The visual decision tree device of claim 10 wherein the sliding card
comprises markers corresponding to a defined scale for classifying the wound or patient.
15
        12.   The visual decision tree device of claim 11 wherein one or more sliding
cards shows a visual decision tree and wherein the housing comprises a view window
through which one or more visual decision trees corresponding to the wound
classification can be viewed.
20

25

ABSTRACT

The present invention relates to methods for consistently designating appropriate treatment protocols for patients, particularly protocols involving wounds or wound prevention. Specifically, the invention relates to methods wherein a patient condition such as a wound is assessed against defined scales for classifying and grading, which assessment is used in a visual decision tree device to identify one or more components of a treatment protocol.

Wound Assessment

Pressure Sore Status Tool (PSST)

Circle the appropriate assessment.

Category						
Classification of Wound (12)	0 — Healed Stage 1	1 — Nurse Action 1 and See Blue Side of Nurse Action Guide / Stage 1 (non-blanchable erythema on intact skin, not resolving within 30 min. of pressure relief)/ Superficial wound Closed Stage 2, 3, or 4, or first degree burns	2 — See Blue Side of Nurse Action Guide / Stage 2 (partial thickness skin loss (abrasion, blister, shallow crater, skin graft donor site, Grade 1 diabetic foot ulcer, or second degree burns	3 — See Red Side of Nurse Action Guide / Stage 3 (penetration to subcutaneous tissue; not past fascia/open surgical wound not past fascia, Grade 2 diabetic foot ulcer, or third degree burns	4 — See Red Side of Nurse Action Guide / Stage 4 (full thickness skin loss with extensive destruction, tissue necrosis, damage to muscle, bone/open surgical wound past fascia, Grade 3 diabetic foot ulcer or, third degree burns (4th degree)	5 — Cannot be staged/ obscured by necrosis → Nurse Action 5
Exudate Amount (13A)	0 — None	1 — Minimal <25% saturation of dressing product per change	2 — Moderate 26-75% saturation of dressing product per change	3 — Heavy >75% saturation of dressing product per change		
Necrotic Tissue Amount (13B)	0 — None	1 — <25%	2 — 26-50%	3 — 51-74%	4 — (>75)	
Undermining (13C)	0 — None	1 — <2cm in any area	2 — 2-4cm involving <50% of wound margins	3 — 2-4cm involving >50% of wound margins	4 — >4cm any area	
Color of Tissue Around Wound (13D)	0 — Normal for ethnic group	1 — Red +/or blanches to touch	2 — Pale, lack of pigment	3 — Dark red, purple +/or non blanching	4 — Black or hypopigmented	
Granulating Tissue (13E)	0 — Skin intact or partial thickness	1 — Beefy red and shiny	2 — Pink	3 — No granulation tissue present		
Peripheral Edema (13F)	0 — None around wound	1 — Non-pitting edema in cm	2 — Pitting edema in cm	3 — Crepitus		
Peripheral Induration (13G)	0 — 0	1 — .0 - 1cm	2 — 1 - 2cm	3 — 2cm or greater		
Pain @ Wound (13H)	0 — No Pain	1 to 2	3 to 4	5 to 6	7 to 8	9 to 10 — Worse Pain Imaginable

Pain scale: 0 1 2 3 4 5 6 7 8 9 10

Nurse Action 1
Nurse Action 3 (17)
Nurse Action 4
Nurse Action 4
Nurse Action 4
Nurse Action 6

Reference numerals: 11, 1a, 1b, 19, 15, 16, 17, 13

FIG. 2

Nurse Action Guide

QUESTION 1

START HERE

What number is checked for Exudate Amount? *(slide to number)*

Nurse Action **2 & 2C**

18

What number is checked for Necrosis Amount?

0 1 2 3 4

Nurse Action **2 & 2A**

Nurse Action **2 & 2B**

QUESTION 2

What number is checked for Undermining?

1 2 3 4

Nurse Action **2 & 2C**

Nurse Action **2 & 2A**

18

Nurse Action Within (...)

0

What number is checked for Undermining?

0 1 2 3 4

Nurse Action **2 & 2A**

Nurse Action **2 & 2B**

18

START HERE

What number is checked for Exudate Amount? *(slide to number)*

QUESTION 1

QUESTION 2

Solutions for Wound Treatment

19

13a
13
13c

1 or 2

What number is
checked for
Undermining?

1	2	3	4	5

Nurse
Action
2A

Nurse Action
2 & 2B

18e

3

Nurse Action
2 & 2A

18f

4

What number is
checked for
_____ mining?

1	2	3	4	5

Nurse Action
2 & 2C

2A

18g

5

2 & 2C

13c   18h

22c

13d

13a
13b

1 or 2

What number is
checked for
Necrosis Amount?

1	2	3	4	5

Nurse Action
2 & 2A

Nurse Action
2 & 2B

18i

19

3

Nurse Action
2 & 2A

18j

4

What number is
checked for
Surrounding Skin?

1	2	3

Nurse Action
2 & 2A

Nurse Action
2 & 2C

18k

5

Nurse Action
2 & 2C

18l

22d

FIG2b

FIG. 2A

QUESTION1

18a 18b 18c 18d

1 2 3 4

question2 question2 question2 question2

1 2 3 4   1 2 3 4   1 2 3 4

A B   A C B   A B   B B C

Care Protocols

19a

25

27

27

28

24 26

23

21

20

16a

16b

19b

22

19a

13q

0

What number is
checked for
Undermining?

13c

| 0 | 1 | 2 | 3 | 4 |

17

Nurse
Action
2 &
2A

Nurse Action
2 & 2B

18m

1

2 & 2A

18N

19

2

What number is
checked for
Undermining?

| 0 | 1 | 2 | 3 | 4 |

Nurse
2 &
2A

Nurse Action
2 & 2C

18o

3

2 & 2C

18P

13c

22a

19

13q

0

What number is
checked for
Necrosis Amount?

13b

| 0 | 1 | 2 | 3 | 4 |

Nurse Action
2 & 2A

Nurse Action
2 & 2B

18g

19

1

Nurse Action
2 & 2A

18r

2

What number is
checked for Color of
Tissue Around Skin?

| 0 | 1 | 2 | 3 | 4 |

Nurse Action
2 & 2A

Nurse Action
2 & 2C

18s

3

Nurse Action
2 & 2C

18t

13d

22b

FIG-20

FIG. 3

Wound Care Protocol Sheet

① Insert text of Tables 1 or 2, Section 1 Here

② Tables 1 or 2, Section 2

2A Tables 1 or 2, Section 2A

2B Table 1, Section 2B

②C Tables 1or 2, Section 2C

③ Tables 1 or 2, Section 3

④ Tables 1 or 2, Section 4

⑤ Tables 1or 2, Section 5

⑥ Tables 1or 2, Section 6

32

31

30

Patient Risk Assessment Record

FIG. 9 F

Braden Scale

Patient ID _____ Assessment Date _____ Clinician _____

Circle appropriate assessment

	1	2	3	4
	1b	2b	3b	

Sensory Perception
Ability to respond meaningfully to pressure-related discomfort

1. Completely Limited
Unresponsive (does not moan, flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation

1b Limited ability to feel pain over most of body surface

2. Very Limited
Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness.

2b Has sensory impairment which limits the ability to feel pain or discomfort over half of the body.

3. Slightly Limited
Responds to verbal commands, but cannot always communicate discomfort or the need to be turned

3b Some sensory impairment which limits the ability to feel pain or discomfort in one or two extremities.

4. No Impairment
Responds to verbal commands, has no sensory deficit which limits the ability to feel pain or voice pain or discomfort

Moisture
Degree to which skin is exposed to moisture

1. Constantly Moist
Skin is kept moist almost constantly by perspiration, urine etc. Dampness is detected every time patient is moved or turned

2. Very Moist
Skin is often, but not always, moist. Linen must be changed at least once a shift

3. Occasionally Moist
Skin is occasionally moist, requiring an extra linen change approximately once a day

4. Rarely Moist
Skin is usually dry, linen only requires changing at routine intervals.

See Moisture Chart

Urinary Incontinence ☐ Night ☐ Always

Fecal Incontinence ☐ Formed or semi-formed ☐ Loose or liquid

Heavy Drainage ☐

Perspiration ☐ Diffuse ☐ Between skin folds ☐ Between skin & mattress

Other _____

Activity
Degree of physical activity

1. Bedfast
Confined to bed

2. Chairfast
Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair

3. Walks Occasionally
Walks occasionally during the day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair

4. Walks Frequently
Walks outside the room at least twice a day and inside room at least once every two hours during waking hours

See Activity Chart

Mobility
Ability to change and control body position

1. Completely Immobile
Does not even make slight changes in body or extremity position without assistance.

2. Very Limited
Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently

3. Slightly Limited
Makes frequent though slight changes in body or extremity position independently

4. No Limitation
Makes major and frequent changes in position without assistance

Nutrition
Usual food intake pattern

1. Very Poor
Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take liquid dietary supplement

1b Is NPO and/or maintained on clear liquids or IVs for more than 5 days.

2. Probably Inadequate
Rarely eats a complete meal and generally only about 1/2 of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take dietary supplement if offered.

2b Gets less than optimum amount of liquid diet or tube feeding

3. Adequate
Eats over half of most meals. Eats a total of 4 servings of protein (meat or dairy products) per day. Occasionally will refuse a meal, but usually will take a supplement if offered

3b Is on tube feeding or TPN regime which probably meets most nutritional needs

4. Excellent
Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does require supplementation

Intake Type ☐ Oral ☐ Enteral ☐ Parenteral

See Nutrition Chart

Friction & Shear

1. Problem
Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositions with maximum assistance. Spasticity, contractures or agitation lead to almost constant friction.

2. Potential Problem
Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against the sheets, chair restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down

3. No Apparent Problem
Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times.

See Friction & Shear Chart

TOTAL _____

FIG. 5

FIG. 6
Nurse Action Report Sheet

Managing Moisture

A Table 3, Section 1A	E Table 3, Section 1E
B Table 3, Section1B	F (circled) Table 3, Section 1F
C Table 3, Section 1C	
D Table 3, Section 1D	

Managing Moisture

G Table 3, Section 2G	K (circled) Table 3, Section 2K
H Table 3, Section 2H	L Table 3, Section 2L
I Table 3, Section 2I	M Table 3, Section 2M
J Table 3, Section 2J	N Table 3, Section 2N

Managing Nutrition

| O Table 3, Section 3O |
| P (circled) Table 3, Section 3P |
| Q Table 3, Section 3Q |
| R Table 3, Section 3R |
| S Table 3, Section 3S |
| T Table 3, Section 3T |
| U Table 3, Section 3U |
| V Table 3, Section 3V |

Friction & Shear

| W Table 3, Section 4W |
| X Table 3, Section 4X |

Wound Care Assessment Record

Name _____

Date of Birth _____ Admission Date: _____

Discharge Date: _____

Patient ID _____ Assessment Date _____

Existing Wound   ☐ Ulcer # _____

New Wound   ☐ Give Ulcer # _____

Clinician _____

Caregiver/Other

Indicate Area

Indicate Size

Indicate Type

Wound Type

☐ Arterial/Ischemic Ulcer
☐ Burn
☐ Neuropathic Ulcer
☐ Perineal
☐ Dermatitis
☐ Pressure Ulcer
☐ Rash
☐ Skin Tear
☐ Surgical Wound
☐ Venous Ulcer
☐ Other _____

Measurements

Length = Longest Axis

Length _____ cm
Width _____ cm
Depth _____ cm

Butterfly Only

Length _____ cm
Width _____ cm
Length _____ cm
Width _____ cm
Depth _____ cm

Right Side   Front   Back   Left Side

Right   Left   Right   Left

Right   Left   Right   Left

Right   Left

Nurse Action Guide

What number is checked for Neutrals Amount?

□ 1 2 3

What number is checked for surrounding skin?

□ 1 2 3

Absorb excess exudate

↓

Maintain moist environment

↓

Nurse Action 3 & 3C

Cleanse/ Debride

↓

Absorb excess exudate

↓

Maintain moist environment

↓

Nurse Action 3 & 3A

Solutions for Wound Treatment

QUESTION 1

19a

19b

16a

QUESTION 2

19c

16b
16c
CARE
PROTOCOLS

27

28

26

21

24 22

FIG. 8

Wound Assessment

US 6,381,577 B1   FIG. 9

Circle the appropriate assessment.

Left panel
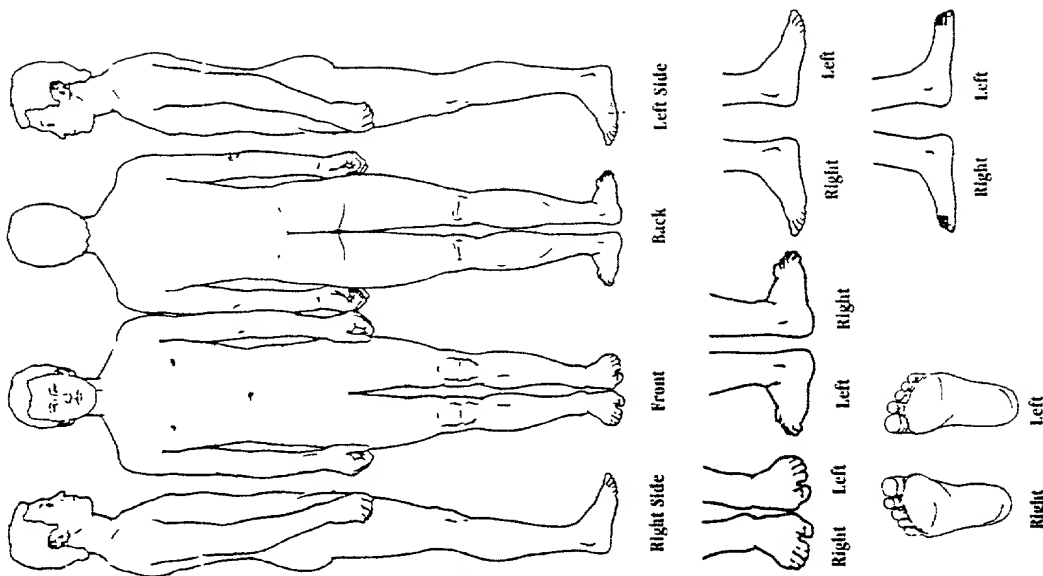
Depth
- Nurse Action 1 and See Blue Side of Nurse Action Guide — Non-blanchable erythema on intact skin
- Partial thickness involving epidermis &/or dermis
- See Blue Side of Nurse Action Guide
- See Red Side of Nurse Action Guide — Full thickness, damage/necrosis of subcutaneous tissue/may extend down to fascia, &/or mixed partial/full thickness; obscured by granulation tissue
- See Red Side of Nurse Action Guide — Full thickness with extensive destruction

Exudate Amount — 1 None · Skant · 3 Small · 4 Moderate · 5 Large

Exudate Type — 1 None or bloody · 2 Serosanguineous thin, watery, pale red/pink · 3 Serous thin, watery, clear · 4 Purulent thin or thick, opaque, tan/yellow · 5 Foul purulent thick, opaque, yellow/green with odor — Nurse Action 4

Necrotic Tissue Amount — None visible · <25% wound bed covered · 25-50% wound covered · 4 >50% <75% wound covered · 5 75-100% wound covered

Necrotic Tissue Type — 1 None visible · 2 White/gray or non-adherent yellow slough · 3 Loosely adherent yellow slough · 4 Adherent, soft black eschar · 5 Firmly adherent, hard black eschar

Undermining — 1 <2cm in any area · 2-4cm <50% of wound margins · 2-4cm >50% of wound margins · 4 >4cm in any area · 5 Thinneling or sinus tract infection — Nurse Action 6

Surrounding Skin Color — 1 Pink or normal for ethnic group · Bright red &/or blanches to touch · White or gray pallor or hypopigmented · 4 Dark red or purple &/or non-blanchable · 5 Black or hyperpigmented — Nurse Action 5 & 6

Granulation — Skin intact or partial thickness · Bright, beefy red 75%-100% wound filled · Bright, beefy red <75% & >25% wound filled · Pink/dull dusky red &/or fills ≤ 25% · 5 No granulation present — Nurse Action 5 & 6
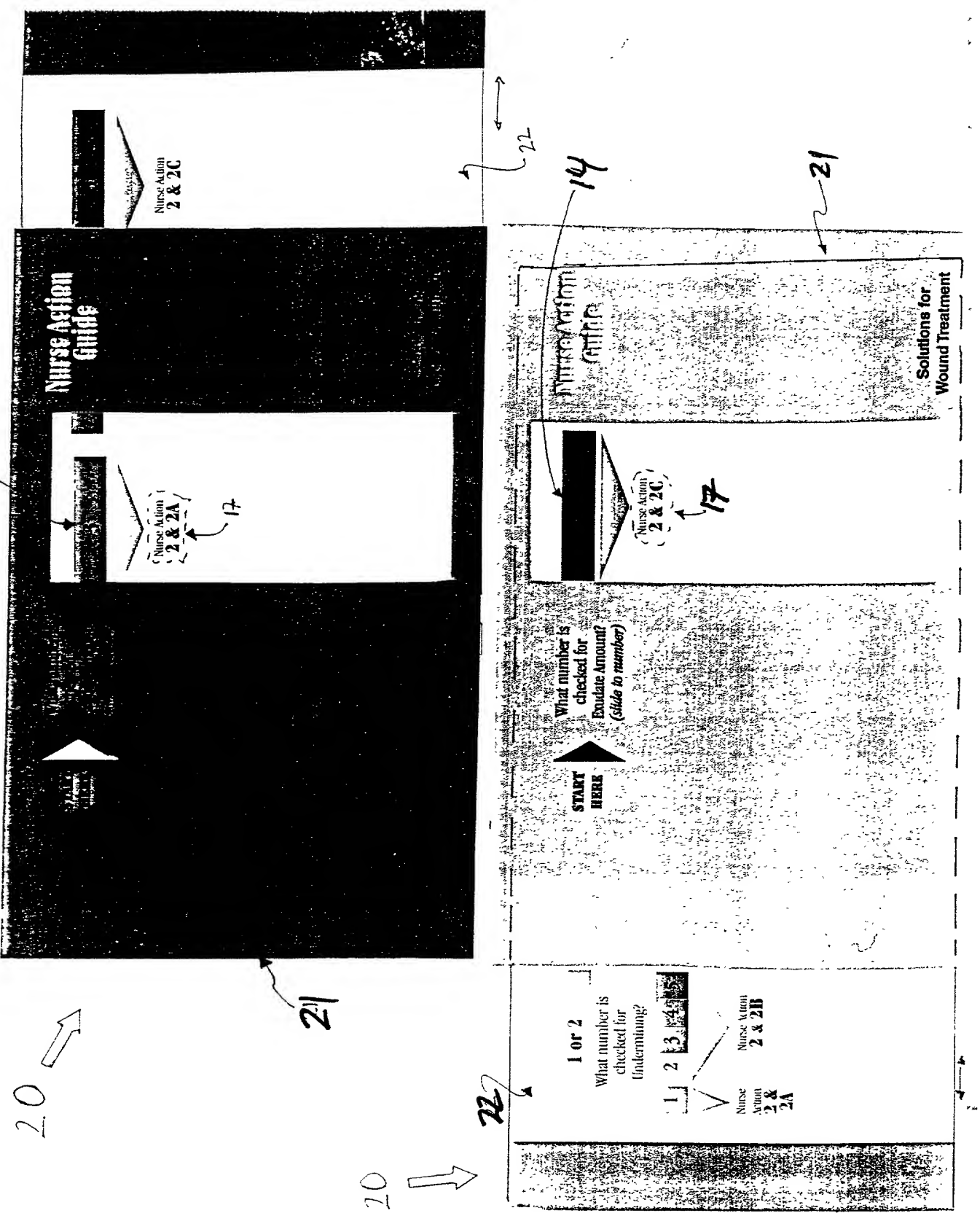
Bates-Jensen. Reprinted with permission Bates-Jensen B.

Right panel

Peripheral Edema — Minimal swelling around wound (Nurse Action 6) · No pitting <4cm around wound · 2 Pitting <4cm around wound · 3 No pitting ≥4cm around wound · 4 Pitting ≥4cm around wound · 5 Crepitus pitting ≥4cm — Nurse Action 5 & 6

Peripheral Induration — Minimal hardness around wound · <2cm around wound · 2-4cm <50% around wound · 2-4cm >50% around wound · >4cm in any area — Nurse Action 5 & 6

Pain @ Wound — 0 No response · 1-3 Minimal · 4-6 Minimal · 7-9 Moderate · 10 Severe pain — Nurse Action 6 & 7

Nutrition — Normal · 75% · 50% · Poor <50% · White or poor oral — Nurse Action 8

Infection — 1 Erythema · 2 Excessive exudate · 3 Increase temp at site · 4 Induration · 5 Infection confirmed

Edges — 1 Indistinct, diffuse, none visible · 2 Distinct, outline visible, attached, even with base · 3 Well defined, not attached to base · 4 Well defined, not attached, rolled under thickened · 5 Well defined, fibrotic, scarred, or hyperkeratotic

Epithelialization — 1 100% covered, skin intact · 2 75-100% covered & or extends >5cm into wound bed · 3 50-75% covered &/or extends to <5cm into wound bed · 4 25-50% covered · 5 <25% covered

Functional Ability — 1 Normal · 2 Slight change · 3 50% · 4 <50% · 5 <25%

Compliance — 1 Motivated 100% · 2 Motivated 75% · 3 Motivated <75% · 4 Motivated 50% · 5 Motivated 25%

Healthy Margin — 1 · 2 · 3 · 4 · 5

How much time spent on assessment?
_____ Minutes

FIG. 10

Nurse Action Guide

Nurse Action 2 & 2C

Nurse Action 2 & 2A

START HERE

What number is checked for Exudate Amount? (slide to number)

Solutions for Wound Treatment

1 or 2

What number is checked for Undermining?

1 2 3 4 5

Nurse Action 2 & 2B

Nurse Action 2 & 2A

Patient ID _____

Assessment Date _____

Clinician _____

Caregiver/Other _____

Add New Wound _____

Ulcer # _____

Existing Wound _____

Status
- ☐ Active
- ☐ Healed

Wound Type
- ☐ Arterial/Ischemic Ulcer
- ☐ Burn
- ☐ Neuropathic Ulcer
- ☐ Perineal
- ☐ Dermatitis
- ☐ Pressure Ulcer
- ☐ Rash
- ☐ Skin Tear
- ☐ Surgical Wound
- ☐ Venous Ulcer
- ☐ Arterial/Ischemic Ulcer
- ☐ Other

Wound Stage
- ☐ Stage I
- ☐ Stage II
- ☐ Stage III
- ☐ Stage IV
- ☐ Unable to stage
- ☐ N/A

Wound Site
- ☐ Ankle
- ☐ Back of Head
- ☐ Coccyx
- ☐ Ear
- ☐ Elbow
- ☐ Forearm
- ☐ Heel
- ☐ Iliac Crest
- ☐ Ischial Tuberosity
- ☐ Knee
- ☐ Lower Leg
- ☐ Sacrum
- ☐ Scapula
- ☐ Thigh
- ☐ Toe(s)
- ☐ Trochanter
- ☐ Vertebrae
- ☐ Other _____

Wound Shape
- ☐ Butterfly
- ☐ Irregular
- ☐ Linear/Elongated
- ☐ Oval
- ☐ Square
- ☐ Round
- ☐ Rectangle

Measurements

Length = Longest Axis

- Length _____ cm
- Width _____ cm
- Depth _____ cm

Butterfly Only
- Length _____ cm
- Width _____ cm
- Length _____ cm
- Width _____ cm
- Depth _____ cm

Wound Placement
- ☐ Left
- ☐ Right
- ☐ N/A
- ☐ Anterior
- ☐ Anterolateral
- ☐ Inferior
- ☐ Lateral
- ☐ Medial
- ☐ Posterior
- ☐ Other _____

Factors Delaying Wound Healing

Blood Related
- ☐ Anemia of any sort
- ☐ Compromised vascular tree (arterial, venous)

Malnutrition
- ☐ Albumin <3.0g/dl

Deficiencies in:
- ☐ Iron
- ☐ Protein
- ☐ Vitamin A
- ☐ Vitamin C
- ☐ Water
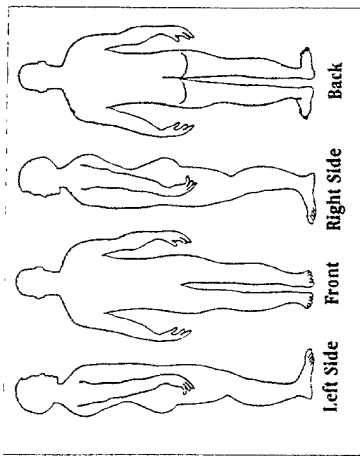- ☐ Zinc

Metabolic Disorders
- ☐ Diabetes
- ☐ Thalasemia

Other
- ☐ Radiation Therapy/ Cytotoxic Drugs
- ☐ Smoking
- ☐ Stress
- ☐ Steroids/Anti-Inflammatory
- ☐ Medications
- ☐ Surgery

Current Primary Diagnosis _____

Indicate proper area

Left Side   Front   Right Side   Back

WSIS

— FIG.11 —

CV283, drawing elements

10   Interactive visual scoring sheet
           first defined scale **11**
           first wound factor **12**
           second defined scale **13**
           second wound factors **14**
           criteria **15** pertaining to wound or patient classification
           connecting indicia **16**
           treatment protocols **17**
           visual decision tree **18**
           markers **19**

20   Visual Decision Tree Device
           housing **21**
           sliding card **22**
           top layer **23**
           bottom layer **24**
           top edge **25**
           bottom edge **26**
           side edge **27**
           view window **28**
           first question **QUESTION1**
           first set of markers **19a**
           first set of arrows **16a**
           a second set of markers **19b**
           second question **QUESTION2**
           second set of arrows **16b**.

30   Wound care protocol sheet
           module **31**

40   Patient data sheet